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EXAMINER	
CARTER, KENDRA D	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/665,240	EKSTROM, TOMMY	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/367,950.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 13-15, 17, 19, 20, 22-25, 30-36, 38, and 42 are provisionally rejected on the ground of nonstatutory double patenting over claims 13-15, 17, 19, 20, 22-25, 30-36, 38, and 42 of copending Application No. 09/367,950. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The US Application No. 09/367,950 discloses a method of prevention and treatment of asthma symptoms, which comprises instructing a patient in need thereof to inhale an effective amount of a composition comprising, in admixture: (a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and (b) a second active ingredient which is budesonide; characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient based on the patient's symptoms, as a treatment and a preventive measure, when the patient experiences an increase in asthma symptoms (see claim 13). The molar ratio of (a) to (b), calculated as formoterol to budesonide~ is from 1:1 to 1:100 or 1;1 to 1:70 (see claims 14 and 25). The first active ingredient can be formoterol fumarate dihydrate (see claim 15) or the R,R enantiomer of formoteml, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt (see claim 16). Formoterol is in a unit dose of from 1 μg to 48 μg or 1 μg to 100

μg for daily dose, including maintenance therapy, which is calculated as formoterol fumarate dihydrate (see claim 17 and 18). The second active ingredient can be the 22R epimer of budesonide (see claim 19). The budesonide is in the form of a unit dose, which delivers 20 μg to 1600 μg to the patient (see claim 10). The particle size of the active ingredients (a) and (b) is less than 10 μm (see claim 22). The composition additionally comprises one or more pharmaceutically acceptable additives, diluents or carriers (see claim 23). The composition can comprise lactose monohydrate (see claim 24). The patient can be instructed to inhale the composition as a rescue medication, as a complement to maintenance treatment of the patient's asthma, as a preventive measure prior to encountering an asthma triggering event, such as cold air, exercise, and exposure to a smoky environment (see claims 30 and 32-36).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of asthma, does not reasonably provide enablement for the prevention of asthma. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of eliminating an individual's tobacco or nicotine usage habit. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 13 is drawn to "a method of prevention and treatment of asthma symptoms, which comprises instructing a patient in need thereof to inhale an effective amount of a composition comprising, in admixture: (a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and (b) a second active ingredient which is budesonide; characterized in that the patient is instructed to inhale the composition on demand, as determined by the

patient based on the patient's symptoms, as a treatment and a preventive measure, when the patient experiences an increase in asthma symptoms."

(2) The breadth of the claims:

Claim 13 embraces preventing asthma. This reads on completely preventing asthma. The specification does not enable the prevention of asthma.

(3) The state of the prior art:

The state of the art regarding preventing asthma is low.

(4) The predictability or unpredictability of the art:

The predictability of preventing asthma is relatively low. Therefore, to one skilled in the art, completely preventing asthma is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to completely preventing asthma is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that completely preventing asthma. The specification discloses that subjects already had asthma and were treated with the

applicant's composition (see page 8 and 9, examples 5 and 6). This does not demonstrate the prevention of asthma because the patent would need to have never had asthma and upon taking the applicant's composition data showing that the patent never developed asthma. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2194.

(7) The quantity of experimentation necessary:

The instant claims read preventing asthma. As discussed above the specification fails to provide any support for completely preventing asthma. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

Therefore, the applicant is enabled to treating asthma, but not to prevent asthma.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 13-15, 17, 18, and 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling (WO 9311773 A1).

Carling et al. teaches suitable daily asthmatic dose of formoterol (as fumarate dehydrate; see page 8, line 6; addresses applicant's claims 13, 15, 17-18, 26-27, 35, 36 and 42 in part) and/or a physiologically acceptable salt and/or solvent thereof and budesonide twice a day (i.e. on demand; see page 4, lines 24-28; page 6, lines 5-30, addresses applicant's claims 13, 35, and 36 in part). The combination of the two drugs have greater efficiency and duration of bronchodilator action, and rapid onset action, which provides rescue medicine, adequate dosing for treating asthma (see page 4, lines 4-21; addresses applicant's claims 13, 30, 32, 33, and 35-42 in part). Formoterol is administered in a suitable daily dose in a range of 6 to 100 μg with a daily dose of budesonide in a range of 50 to 4800 μg (see page 6, lines 24 and 26; addresses

applicant's claims 17, 18, 20, 21, and 27-29). The dosages strongly depends on the patient (age, weight etc.), severity of disease (mild, moderate, severe asthma etc..); see page 6, lines 27-29. The ratio of formoterol to budesonide is in the range of 1:4 to 1:70, which can be administered separately in the same ratio (see page 6, lines 17-20; addresses applicant's claims 14 and 25). Non-toxic and chemically inert diluents, additives, and carriers are used in the composition, such as lactose (see page 7, lines 1-3; addresses applicant's claim 23 and 24). The amounts of active agents per dose of inhalation are disclosed on pages 7-9, which calculate up to 8 inhalation per day without going over the maximum daily dosage.

Carling et al. does not teach instruction for the patient to inhale, on demand, as determined by the patient, based on the patient's symptoms, when (1) the patient experiences an increase in asthma symptoms as set forth in applicant's claim 13; (2) as a complement to maintenance treatment of the patient's asthma as set forth in applicant's claims 32, 35, 37-39 and 41; or (3) when the patient is expecting to encounter an asthma trigger, wherein the triggering event is selected from the group consisting of exposure to cold, air, exercise, or a smoky environment (applicant's claims 33, 34 and 36. Carling et al. does not instruct the patient to take a second composition, comprising a glucorticosteroied, on a regular basis as a maintenance treatment (applicant's claim 33) or to inhale additional doses as needed to improve control and provide acute relief (applicant's claim 42). Carling et. al. also does not the particle size of the active ingredients (applicant's claim 22).

To one of ordinary skill in the art, it would have been obvious to combine the method of Carling et al. and instructing the patient to inhale, on demand in any of the circumstances detailed in claims 32-49 and 41-42 because Carling et al. teaches that the dosages strongly depends on the severity of disease, whether mild, moderate, or sever asthma (see pg 6, lines 27-29), and the suitable daily dosage is up to 8 inhalation (see page 7-9).

The motivation to combine the methods and compositions of Carling et al. and instructing the patient to inhale, on demand in any of the circumstances detailed in claims 32-49 and 41-42 because Carling et al. teaches that the dosages strongly depends on the severity of disease and to achieve maximum benefit of daily dosage recommended. It is noted by Carling et al. that the combination of formoterol with budesonide is well known to be benefical for the treatment of asthma (see page 4, lines 4-21). Moreover, if the patient is experiencing acute asthmatic attack even with ongoing twice a day dosing regimen, the patient can still safely inhale an additional 6 inhalations without going over the maximum suitable daily dosage. In general, Carling et al. teaches therapeutic relief from asthmatic attack. The skilled artisan would have been motivated to instruct the patient to use the Carling et al. composition as needed on the bases of up to 8 inhalations a day is for reasonable expectation of successfully achieving maximum benefit in the treatment of any level of the asthma condition,

including an increase in asthma symptoms, acute asthmatic condition, maintenance treatment, and common asthma triggers.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Carling et al. and the particle size of active agents set forth in claim 22, because they are known by a skilled pharmacologist and represent conventional formulations.

(2) Claim 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carling et al. of record as applied to claims 13-15, 17, 18, and 20-42 above, in view of Aberg et al. (U.S.Patent 5,795,564) and in further view of Ryrfeldt et al. (Biochemical Pharmocology, 1989, 38(1), pages 17-22).

Carling et al. teaching are as applied to claims 13-15, 17, 18, and 20-42 above.

Carling et al. does teach the (R,R) enantiomer of formoterol set forth in claim 16 and the 22R epimer of budesonide set forth in claim 19.

Aberg et al. teaches (R, R) isomer of formoterol as required by claim 16 is a potent bronchodilator with reduced adverse effects in treatment of asthma. (abstract, column, 1, lines 25-35).

Ryrfeldt et al. teaches that the 22R epimer of budesonide is more potent in the treatment of bronchial asthma than 22S epimer (see page 17, column 1, paragraph 2, lines 12-15).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Carling et al. and the (R,R) enantiomer of formoterol and the 22R epimer of budesonide because Aberg et al. and Ryrfeldt et al. teach that these specific isomers possess potent asthmatic effect.

The motivation employ the (R,R) isomer of formoterol and 22R epimer of budesonide in the Carling et al. composition is because there is a reasonable expectation of successfully treating asthmatic patients with a more effective medication with reduced adverse effects.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER